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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/085,637	02/28/2002	Donald J. McMichael	KCX-518A (17507A)	5368
22827	7590	02/29/2008		
DORITY & MANNING, P.A. POST OFFICE BOX 1449 GREENVILLE, SC 29602-1449			EXAMINER BUL, LUAN KIM	
			ART UNIT 3728	PAPER NUMBER
			MAIL DATE 02/29/2008	DELIVERY MODE PAPER

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte DONALD J. MCMICHAEL and MARK E. FOSTER

Appeal 2008-0198
Application 10/085,637
Technology Center 3700

Decided: February 29, 2008

Before ERIC GRIMES, LORA M. GREEN, and FRANCISCO C. PRATS,
Administrative Patent Judges.

GRIMES, *Administrative Patent Judge.*

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a surgical kit with an accessory items container. The Examiner has rejected the claims as obvious. We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

BACKGROUND

“Various medical procedures are simplified by providing the physician with a kit that contains the majority, if not all, of the necessary medical articles or implements that the physician or surgical staff will need to complete a particular procedure” (Specification 1). “These kits reduce the time spent by hospital personnel gathering the appropriate articles that are

required for a particular procedure and ensure that the surgeon has each article at hand at the appropriate point in the procedure” (*id.*).

The Specification teaches a surgical kit that “includes a tray having a plurality of recesses formed therein for receiving surgical articles or implements useful in performing a particular surgical procedure” (*id.* at 2). “The kit may also include any combination of ‘accessory’ surgical items” and also “includes an accessory item container that may be received in a container recess defined in the tray” (*id.* at 3).

DISCUSSION

1. CLAIMS

Claims 1-23, 25, and 26 are on appeal. Claim 24 is also pending and has been indicated to be allowable (Answer 5).

Claims 1 and 15 are representative and read as follows:

Claim 1: A surgical kit, comprising:

a tray, said tray further comprising a plurality of recesses formed therein for receiving surgical articles useful in performing a particular surgical procedure;

a substantially rigid accessory item container received in a container recess defined in said tray said container configured for holding objects only inside of said container before being opened by a user;

said container recess defining a nesting location for said container;

said container comprising a base member and a lid configured with said base member, said container removable from said tray; and

a securing device configured between said base member and said lid.

Claim 15: A percutaneous endoscopic gastrostomy (PEG) kit, comprising:

a tray comprising a plurality of recesses disposed therein, each said recess adapted to hold articles useful in performing a percutaneous endoscopic gastrostomy (PEG) procedure;

a container adapted to fit at least partially within the tray, the container adapted to rest upon a planar surface defined within said tray, said container comprising a base member and a reclosable lid; and

wherein said container stores accessory items useful in performing the PEG procedure, and wherein the accessory items include at least a drape.

2. OBVIOUSNESS

Claims 1-23, 25, and 26 stand rejected under 35 U.S.C. § 103 as obvious in view of Ross,¹ Harrison,² and Rudnick.³ Appellants separate the rejected claims into two groups for argument, the first group containing claims 1-14, and the second group containing claims 15-23, 25 and 26 (Appeal Br. 4).⁴ Claims 2-14 therefore stand or fall with claim 1 and claims 16-23, 25, and 26 stand or fall with claim 15. 37 C.F.R. § 41.37(c)(1)(vii).

The Examiner relies on Ross as disclosing a kit “for holding surgical articles comprising a tray (13) having a plurality of planar surfaces with a plurality of recesses for holding surgical articles, a removable container (20) containing surgical articles ... disposed within at least one of the planar surfaces/container recess” (Answer 4). The Examiner further finds that Ross discloses that “the container (20) must be removed from the tray prior to access to the articles,” but does not disclose “the container being a substantially rigid container having a base member and a lid” (*id.*).

The Examiner relies on Harrison as disclosing a kit comprising “a tray (24) having recess and a container (26) disposed within the tray including a base member (72) and a lid (70) that define an interior space for holding an article” (*id.*). The Examiner relies on Rudnick as disclosing a kit comprising

¹ Ross et al., US 5,318,543, Jun. 7, 1994.

² Harrison, US 5,392,918, Feb. 28, 1995.

³ Rudnick et al., US 6,039,183, Mar. 21, 2000.

⁴ Appeal Brief filed July 21, 2005.

“a tray (22) having a plurality of recesses disposed therein and a container (24) adapted to fit at least partially within the tray including a base member (44) and a lid (46)” (*id.*). The Examiner further relies on Rudnick as disclosing that the container comprises a securing device (*id.*).

The Examiner concludes that it “would have been obvious to one having ordinary skill in the art in view of Harrison and Rudnick ... to modify the container of Ross ... so that the container comprises a substantially rigid container having a base and a lid that define an interior space for holding the articles for better protecting the articles and to facilitate opening and/or closing the container” (*id.*). With regard to claim 15, the Examiner concludes that it would have been obvious to one having ordinary skill to use the container “to hold accessory articles such as the [drape] of Ross ... because the selection of the specific articles for the container would have been an obvious matter of design choice” (*id.* at 4-5).

We conclude that the Examiner has set forth a *prima facie* case that claims 1 and 15 would have been obvious to the ordinary artisan. Ross discloses a kit for surgical instruments (Ross, col. 1, ll. 8-10) that comprises a tray that “provides recesses which correspond in dimension and shape to the various components of the kit packaged therein” (*id.* at col. 2, ll. 21-33). Ross also discloses that certain kit components are packaged in a sealed pouch that is disposed within a recess in the tray (*id.* at col. 2, ll. 63-66). Ross also discloses that the kit can also comprise a drape, either placed in a tray recess or overlying the tray (*id.* at col. 2, ll. 21-23 and 40-43).

Harrison discloses a surgical kit that “comprises a hollow, generally rectangular tray,” a holder for a guide-wire, and a lid, wherein “the tray 24

includes a recess for releasably securing the holder 26 with the guide-wire 22E therein, and a plurality of recessed areas for holding” other components (Harrison, col. 4, ll. 13-21; Fig. 7). “The holder 26 . . . is itself a sealed member” (*id.* at col. 4, ll. 29-30). Harrison also discloses that certain of the components “are packaged together within a foil pouch” (*id.* at col. 3, ll. 59-63).

Rudnick discloses a kit for packaging an “aortic arch graft in configuration for implantation,” comprising a tray having a “depression formed therein for accommodating the main tube and at least one of the branch tubes of the graft” and an insert within the tray that includes a depression formed in one surface for accommodating another of the branch tubes of the graft (Rudnick, abstract). Rudnick also discloses that the insert is folded so that “detent members” (in the corners of the unfolded insert) interlock to hold the insert in a folded configuration (*id.* at col. 3, ll. 51-55, Figs. 5 and 6).

We agree with the Examiner that it would have been *prima facie* obvious to one of ordinary skill in the art to combine the teachings of Ross, Harrison and Rudnick and thereby arrive at the kit defined by claims 1 and 15. Ross discloses a tray for surgical equipment that has a pouch (i.e., a container) for holding surgical supplies and disposed within the recess of a tray, where the pouch is configured for holding objects only inside of the container before being opened by a user. Thus, Ross discloses all of the elements of claim 1 with the exception of a “substantially rigid container.”

Both Harrison and Rudnick disclose rigid containers that hold surgical supplies and are part of a surgical kit. The rigid containers of both Harrison

and Rudnick have a base member and a lid (Harrison, col. 4, ll. 29-30, Fig. 7; Rudnick, Fig. 7). The rigid container of Harrison is disposed within a tray recess (Harrison, col. 4, ll. 17-19). The rigid container of Rudnick comprises interlocking detent members; i.e., a securing device (Rudnick, col. 3, ll. 51-55).

It would have been obvious to one ordinary skill in the art to substitute the rigid container taught by Harrison and Rudnick for the pouch of Ross, because the references disclose that both pouches and rigid containers were known in the art for holding surgical items in a kit. Those of skill in the art would have recognized that pouches and substantially rigid containers would work equally well for such a purpose and one could be substituted for the other.

We also agree with the Examiner that the cited references would have made obvious the kit defined by 15. Ross discloses a drape as an element of the disclosed kit (Ross, col. 2, ll. 40-43). One of skill in the art would be motivated to include a drape in the kit made obvious by the combined references in order to preserve sterility of the drape, until the drape is required by the surgeon. The interlocking-detents securing device taught by Rudnick meets the “reclosable lid” limitation of claim 15.

Appellants argue that the element of “a substantially rigid container that has a base member and a lid that is configured for holding objects only inside of the container before being opened by a user” is not taught or suggested by the combination of Ross, Harrison, and Rudnick (Appeal Br. 9-10). Appellants further argue that “both Rudnick ... and Harrison specifically teach ... a blister insert or container in which objects are held at

least partially on the outside of the container” and “[m]odification of the references so that the container was made to hold objects only on the inside would eliminate features that are of ‘considerable importance’ and ... would render the containers unsatisfactory for their intended purpose” (*id.* at 8). Thus, Appellants argue, there can be no suggestion or motivation to make the proposed modification (*id.* at 8-9).

We do not find this argument to be persuasive. The Examiner’s reasoning (with which we agree) is not that it would have been obvious to modify the substantially rigid containers of Rudnick and Harrison to hold supplies entirely on the inside, as Appellants argue, but that it would have been obvious to modify the pouch of Ross to be substantially rigid, as suggested by the substantially rigid containers of Harrison and Rudnick. “The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.” *KSR Int’l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1739 (2007). “[W]hen the question is whether a patent claiming the combination of elements of prior art is obvious,” the relevant issue is “whether the improvement is more than the predictable use of prior art elements according to their established functions.” *Id.* at 1740. The combination of the pouch of Ross, for holding surgical supplies, with the substantially rigid containers of Harrison and Rudnick, for holding surgical supplies, appears to be nothing more than the combination of old elements to yield predictable results.

With regard to claim 15, Appellants argue that there is no suggestion or motivation to combine Rudnick, Harrison and Ross, and to further modify this combined device to arrive at the invention of claim 15 (Appeal Br. 11).

Appellants argue that Rudnick and Harrison do not disclose drapes (*id.* at 11-12), and that “Ross ... directs one of ordinary skill in the art to loosely place the drape into a recess of the tray” (*id.* at 12). Appellants also argue that the “intended purpose of Ross ... is to provide for a kit that reduces packaging material” and modification of Ross to place the drape in a container would increase the amount of packaging and frustrate that purpose (*id.* at 12-13). Thus, Appellants argue, a suggestion or motivation to make the modification is not in the references (*id.* at 13).

We do not find this argument to be persuasive. Although Ross teaches that one of the purposes of a kit generally is to reduce packaging by packaging kit items together, Ross also specifically suggests including a drape within a recess of the disclosed kit. (Ross, col. 2, ll. 40-43: “[O]ptional additional kit components such as a sterile drape . . . could also be placed in this recess if desired.”) The combination of a drape with the surgical kit made obvious by Ross, Harrison, and Rudnick appears to be nothing more than the combination of old elements to yield predictable results.

SUMMARY

The Examiner’s rejection is supported by the preponderance of the evidence of record. We therefore affirm the rejection of claims 1-23, 25, and 26 under 35 U.S.C. § 103.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

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